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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,292	11/26/2001	Claes Ohlsson	102296-100	8841

7590 08/08/2003  
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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/08/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/994,292

Applicant(s)

OHLSSON ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 8-14 and 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6, 7, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ..

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### **First Office Action on the Merits**

#### ***Election/Restrictions***

1. Applicant's election with traverse of Group II and of the species 17 $\beta$ -estradiol in Paper No. 7 is acknowledged. However, no reason(s) was given for said traversal.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 1-5, 8-14 and 17-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Claims 6, 7, 15 and 16 stand rejected as indicated below.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 6, 7, 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In order to satisfy the written-description requirement, the specification must (a) describe every element of the claimed invention in sufficient detail so that the skilled

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artisan in the art would recognize that applicant possessed the claimed invention at the time of filing and (b) enable those skilled in the art to make and use the full scope of the claimed invention without undue experimentation. That is, the present specification must describe the invention with all its claimed limitations, not by what makes it obvious.

The present specification lacks an adequate description of the claimed subject matter commensurate in scope with the instant claims because it identifies the claimed compounds by a functional characteristic, i.e., an ER $\alpha$  selective compound, but does not correlate said characteristic with any known structure(s). In essence, the present specification describes what the claimed compound does and not what it is outside of the two compounds disclosed therein. In other words, the claimed invention depends upon finding a compound that acts selectively at the  $\alpha$  subset of estrogen receptors however, the present disclosure fails to correlate said characteristic with any known structure(s). Therefore, the skilled artisan in the art would first have to obtain a compound having said characteristic in order to practice the claimed invention. Because of the lack of guidance of any correlation between known compounds and the claimed activity, the amount of experimentation necessary to practice the claimed invention would be considered undue to the skilled artisan in the art.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 6, 7, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Heckenmuller et al. ('673).

Heckenmuller et al. teach a pharmaceutical composition comprising  $17\beta$ -estradiol useful for transmucosal administration (see the entire article, especially Example 4).

The composition taught by the reference is encompassed by the instant claims.

7. Claims 6, 7, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lanquetin et al. ('867).

Lanquetin et al. teach a pharmaceutical composition comprising  $17\beta$ -estradiol for oral administration useful in treating estrogen deficiencies in menopausal women (see the entire article, especially col. 6, lines 25-65). The composition taught by the reference is encompassed by the instant claims.

8. Claims 6, 7, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Collins ('557).

Collins teaches a pharmaceutical composition comprising  $17\beta$ -estradiol for treatment of coronary heart disease (see the entire article, especially Abstract; claims 1-3). The composition taught by the reference is encompassed by the instant claims.

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9. Claims 6, 7, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Bodor et al. ('298).

Bodor et al. teach a pharmaceutical composition comprising derivatives of  $17\beta$ -estradiol, such as  $17\beta$ -[(1-methyl-1,4-dihydro-3-pyridinyl)carbonyloxy]estra-1,3,5(10)-trien-3-ol, useful for weight control (see the entire article, especially Abstract; col. 46, lines 25-68). The composition taught by the reference is encompassed by the instant claims.

10. Claims 6, 7, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ke et al.

Ke et al. teach a composition comprising a nonsteroidal, potent estrogen agonist/antagonist, CP-336,156 and its binding affinity to the human  $\alpha$ -estrogen receptor (see the entire Abstract). The composition taught by the reference is encompassed by the instant claims.

#### ***Other Matters***


11. It should be noted that recitation of the intended use of a composition does not impart patentability to said composition.

***Telephon Inquiry***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308- 2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
August 6, 2003